REMARKS

Claims 1, 2, 6, and 7 are currently pending in the application. Claims 1 and 6 are in independent form.

Applicants wish to express their appreciation for the courtesies extended Applicants' representative, Amy E. Rinaldo, during a telephonic interview conducted on September 19, 2006.

Claims 1, 2, 6, and 7 stand rejected under 35 U.S.C. §102(b) as being anticipated by the Pittenger et al., patent. Reconsideration of the rejection under 35 U.S.C. §102(b), as anticipated by the Pittenger et al., patent, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The Office Action has held that Pittenger et al., patent discloses a method of administering stem cell products such as mesenchymal stem cells (MSCs) directly to a heart or directly to the damaged portion of the myocardium. The Pittenger et al., patent also discloses that MSC therapy can be provided by several routes of administration including intravenously, intracoronarily, or directly to the heart. The Office Action concludes that the Pittenger et al., patent discloses a method having an identical active step and identical structural elements while achieving identical effects as recited in the presently pending independent claims.

When read more specifically, the Pittenger et al., patent discloses that stem cells themselves must be cultured *in vitro* prior to transplantation into the body. It was previously unknown that stem cell products, such as those recited in the presently pending claims, could be used in treating heart failure. The presently pending claims recite use of stem cell products that are transplanted directly into the body of a patient without need of *in vitro* differentiation or alteration. It was previously thought that the stem cells must be differentiated or genetically altered

prior to insertion into the body in order for the stem cells to achieve the desired function. The presently claimed invention instead recites that the products from the stem cells can be placed directly into a location for treating heart failure and that the stem cell products alone are sufficient for treating heart failure. The cited prior art reference discloses the use of altered or differentiated stem cells for treating heart failure. The Office Action has held that the stem cells disclosed in the prior art are identical to the stem cell products recited in the pending claims; however, there is absolutely no disclosure that connects the stem cells disclosed in the prior art and stem cell products as recited in the presently pending independent claims. The stem cell products recited in the presently pending claims are secretions from stem cells found in stem cells containing supernatant, not merely stem cells as recited in the prior art.

There is no disclosure in the Pittenger et al., patent that the use of products formed by stem cells alone, without the presence of the stem cells, could be used in treating heart failure, improving cardiac function, enriching or regenerating damaged myocardium. All that is disclosed by the Pittenger et al., patent is that stem cells can be administered to improve function after a myocardial infarction. As recited in MPEP 2111.01 Applicant can be its own lexicographer. In other words, Applicant can assign its own meaning to a word, as long as that the definition of the word is sufficiently clear in the specification. Multi-Form Desiccants, Inc. v. MedZam, Ltd., 133 F.3d 1473 and Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350. What is required is that the claims, when read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention. The Court has held in Shatterproof Glass Corp. v. Libbey Owens Ford Company, 758 F.2d 613 that the statute requires no more. While the term here is not being used contrary to its ordinary meaning, the Court has also held that a term can be used in a matter contrary to or inconsistent with one or more of the ordinary meanings if the written description clearly redefines the term (CEG Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350). In the specification as filed, stem cell products are clearly defined on page 4, lines 23-30, wherein there is disclosed that the invention can utilize "stem cells, supernatant

from stem cells, the secretions resulting from the interaction of stem cells and other cells (e.g. stem cell products) . . ." Thus, the term "stem cell products" has been clearly defined to one of skill in the art and such, the term "stem cell products" are not disclosed in the Pittenger, et al. patent. Absent a teaching in the Pittenger et al., patent for the use of stem cell products for treating myocardial infarction, the claims are patentable over the Pittenger et al., patent and reconsideration of the rejection is respectfully requested.

Claims 1, 2, 6, and 7 stand rejected under 35 U.S.C. §102(b) as being anticipated by the Tomita et al., reference. Reconsideration of the rejection under 35 U.S.C. §102(b), as anticipated by the Tomita et al., reference, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The Office Action has held that the Tomita et al., reference discloses a method of treating heart failure, improving cardiac function, enriching or regenerating damaged myocardium by administering stem cell products, such as MSCs, directly to the heart or damaged myocardium. Further, the Tomita et al., reference discloses that transplantation of MSCs improved infarcted heart function, which is identical to the methods recited in the presently pending independent claims.

When read more specifically, the Tomita et al., reference discloses that stem cells themselves must be cultured *in vitro* prior to transplantation into the body. It was previously unknown that stem cell products, such as those recited in the presently pending claims, could be used in treating heart failure. The presently pending claims recite use of stem cell products that are transplanted directly into the body of a patient without need of *in vitro* differentiation or alteration. It was previously thought that the stem cells must be differentiated or genetically altered prior to insertion into the body in order for the stem cells to achieve the desired function. The presently claimed invention instead recites that the products from the

stem cells can be placed directly into a location for treating heart failure and that the stem cell products alone are sufficient for treating heart failure. The cited prior art reference discloses the use of altered or differentiated stem cells for treating heart failure. The Office Action has held that the stem cells disclosed in the prior art are identical to the stem cell products recited in the pending claims; however, there is absolutely no disclosure that connects the stem cells disclosed in the prior art and stem cell products as recited in the presently pending independent claims. The stem cell products recited in the presently pending claims are secretions from stem cells found in stem cells containing supernatant, not merely stem cells as recited in the prior art.

There is no disclosure in the Tomita et al., reference that the use of products formed by stem cells alone, without the presence of the stem cells, could be used in treating heart failure, improving cardiac function, enriching or regenerating damaged myocardium. All that is disclosed by the Tomita et al., reference is that stem cells can be administered to improve function after a myocardial infarction. Absent a teaching in the Tomita et al., reference for the use of stem cell products for treating myocardial infarction, the claims are patentable over the Tomita et al., reference and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not discussed above are ultimately dependent upon at least one of the independent claims discussed above. No prior art reference makes up for the deficiencies of that reference as applied against the independent claims as no prior art reference discloses or suggests the invention as set forth in the claims as discussed in detail above.

Applicants respectfully request to be contacted by telephone if any remaining issues exist.

In summary, the presently claimed invention is in condition for allowance, which allowance is respectfully requested. If any remaining issues exist, Applicants respectfully request to be contacted by telephone at (248) 539-5050.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC

Amy E. Rinaldo, Reg. No. 45,791
30500 Northwestern Highway
Suite 410
Farmington Hills, Michigan 48334
(248) 539-5050

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